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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,570	03/21/2005	Hiroki Ogawa	Q86961	5034

23373 7590 09/05/2007

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	
MAIL DATE	**DELIVERY MODE**
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,570	OGAWA ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/05, 12/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The disclosure is objected to because of the following informalities: On page 13, lines 19-23, a brief description for Figures 6A-6C should be included here. On page 14, lines 5-9, a brief description for Figures 9A-9B should be included here. On page 14, lines 10-14, a brief description for Figures 10A-10B should be included here. On page 14, lines 15-19, a brief description of Figures 11A-11B should be included here. On page 14, lines 20-24, a brief description of Figures 12A-12C should be included here.

Appropriate correction is required.

3. Figures 1-4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. Claims 1 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 8-9 of claim 1, the phrase "the a centrifugal force pressurizing reverse direction" lacks antecedent basis, and is indefinite since a direction **opposite** to the centrifugal force pressurizing **reverse** direction would be the same as the centrifugal force pressurizing direction.

In order for this phrase to make proper sense, Applicants are requested to recite that the downstream portion of the flow channel is elongated in a direction opposite to the centrifugal force pressurizing direction. On line 13 of claim 1, the phrase "the centrifugal force pressurizing direction side" lacks antecedent basis. On the last line of claim 1, the phrase "the blood introduced" should be changed to –blood introduced—since a blood sample has not been previously positively recited in the claim.

On line 3 of claim 4, the phrase "the plasma" lacks antecedent basis since no plasma sample was positively recited in claim 1, only a plasma separating means.

On line 27 of claim 6, the phrase "the blood introduced" should be changed to –blood introduced—since a blood sample has not been previously positively recited in the claim. On line 35 of claim 6, the phrase "the plasma separated" should be changed to –plasma separated—since no plasma sample has been previously positively recited.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2003-83958 (submitted in the Information Disclosure Statement filed on March 21, 2005).

JP 2003-83958 teaches of a blood analyzer and blood analyzing method substantially as claimed comprising a flow channel connected between a blood inlet port and an outlet port, and a plasma separating means disposed midway between the flow channel. The channel is U-shaped so that it has an upstream portion elongated along a centrifugal force pressurizing direction and a downstream portion elongated in a direction opposite to the centrifugal force pressurizing direction. The plasma separating means is positioned between the upstream and downstream portions of the channel, and includes a blood corpuscle accumulation means that helps enhance the operative stability of the blood analyzer by allowing the upstream and downstream portions of the channel to remain in contact with one another in the upper space of the blood corpuscle accumulation means. The lowermost portion of the U-shaped channel constitutes the blood corpuscle accumulation means. The analysis apparatus also comprises analysis means for analyzing components present in plasma disposed between the plasma separating means and the outlet port. A blood collecting needle is attachable to the inlet port so that a blood sample can be collected directly from a patient into the device. A method for using the device comprises collecting a blood sample directly from a patient into the device through the inlet port, centrifuging the device so that the blood corpuscles become disposed in the blood corpuscle

accumulation means, and feeding the resulting plasma in both the upstream and downstream portions of the channel to the plasma analysis means located downstream of the blood corpuscle accumulation means. See the abstract and Figures 1 and 10 of JP 2003-83958.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al (JP 2001-258868, submitted in the Information Disclosure Statement (IDS) filed on March 21, 2005, English language equivalent is US 2003/0114785) in view of Boyd et al (US 5,919,711, submitted in the IDS filed on December 5, 2005).

Kikuchi et al teaches of a blood analyzer and blood analyzing method substantially as claimed comprising a flow channel connected between a blood inlet port and an outlet port, and a plasma separating means disposed midway between the flow channel. The channel is U-shaped so that it has an upstream portion elongated along a centrifugal force pressurizing direction and a downstream portion elongated in a direction opposite to the centrifugal force pressurizing direction. The plasma separating means is positioned between the upstream and downstream portions of the channel in the lowermost portion of the U-shaped channel. The analysis apparatus also comprises analysis means for analyzing components present in plasma disposed between the plasma separating means and the outlet port. A blood collecting needle is attachable to the inlet port so that a blood sample can be collected directly from a patient into the device. A method for using the device comprises collecting a blood sample directly from a patient into the device through the inlet port, centrifuging the device so that the blood corpuscles become disposed in the lowermost portion of the U-shaped channel, and feeding the resulting plasma in the downstream portion of the channel to the plasma analysis means. See Figures 2 and 13, and paragraphs 0026-0027 and 0045 in Kikuchi et al (US 2003/0114785, English language equivalent to JP 2001-258868). Kikuchi et al fail to teach that the plasma separating means located in the lowermost portion of the U-shaped flow channel includes a blood cell fraction collection container that allows plasma in both the upstream and downstream portions of the flow channel to remain in contact with one another in an upper space of the blood cell fraction container.

Boyd teaches of an analytical cartridge that can be used to analyze blood and separate blood cells from plasma. The cartridge comprises a deposition well 38 where a blood sample is

deposited. After a blood sample is placed into the cartridge, a cap 18 is closed and the cartridge is placed into a centrifuge. Sufficient centrifugal force is applied to the cartridge 10 to ensure that the blood cells 46 are concentrated into a separation well 48. The deposition well 38 is connected to the separation well 48 by inlet passageway 52. The separation well 48 is then connected to a test well 54 by way of an outlet passageway 56. Centrifuging of the cartridge 10 results in the separation of the blood plasma from the solid or cellular components of blood located in the separation well 48. Substantially solids-free plasma remains in portions of the outlet passageway 56 and the inlet passageway 52 leading to the separation well 48. After completion of the centrifuging step, the substantially solids-free plasma located in both the inlet and outlet passageways 52 and 56 is transported through the outlet passageway 56 towards a test well 54 by pressure applied to the deposition well 38. Different reagents can be placed in the test well 54 for reacting with the plasma in order to detect a certain analyte therein such as glucose, calcium, cholesterol, hemoglobin, etc. See Figures 1, 4-5, lines 62-67 in column 3, lines 1-64 in column 4 and lines 8-46 in column 6 of Boyd et al. Therefore, Boyd et al teach of a cartridge for separating plasma from blood cells in a whole blood sample, wherein a substantially U-shaped flow channel extends between an inlet port and an outlet port, and a blood cell fraction container is located at the lowermost end of the U-shaped channel for collecting blood cells therein upon centrifugation of the cartridge, and for allowing the resulting plasma in both sections of the channel located upstream and downstream from the blood cell collection container to remain in contact with one another and be transported to a testing area 54 located downstream of the collection container.

Based upon the combination of Kikuchi et al and Boyd et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide a blood cell fraction container in the lowermost portion of the U-shaped flow channel taught by Kikuchi et al since Boyd et al disclose that a blood cell collection container in a similar type of device prevents a U-shaped flow channel from becoming plugged by blood cells when the device is centrifuged to separate blood cells from plasma, thus allowing plasma located both before and after the lowermost portion of the U-shaped channel where the blood cells separate to flow past the lowermost portion and reach a plasma analysis section located downstream of the lowermost portion, where more accurate results can be obtained by having the entire plasma portion of a blood sample at the analysis section rather than only a small portion of the plasma.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Lake et al, Horiike et al (JP 2002-267677) and Oki et al (article from Jpn. Journal of Appl. Phys.) who teach of centrifugation devices for separating plasma from blood cells; and Petithory who teaches of a method and apparatus for controlling fluid movement through a microfluidic device.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 28, 2007

Maureen M. Wallenhorst
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